IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: C. R. BARD, INC. PELVIC REPAIR
SYSTEM PRODUCTS LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

CAROLYN JONES,	)
	)
Plaintiff,	)
	) CIVIL ACTION FILE
v.	)
	) NO. 2:11-cv-00114
C. R. BARD, INC.,	)
	)
Defendant.	)
_____	)

PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT ON DEFENDANT C. R. BARD'S AFFIRMATIVE DEFENSES AND BRIEF IN SUPPORT THEREOF

COMES NOW Plaintiff, Carolyn J. Jones, and files this her Motion for Partial Summary Judgment on Defendant C. R. Bard, Inc.'s (hereinafter "Defendant" or "Bard") Affirmative Defenses and Brief in Support Thereof and shows the Court as follows:

I. STATEMENT OF FACTUAL AND PROCEDURAL BACKGROUND

A. General Case Background

These bellwether cases arise from the implantation of the "Avaulta Plus" or "Avaulta Solo" devices, which are synthetic surgical mesh products that were designed, manufactured, marketed and sold by Bard for implantation in the female pelvic floor region to provide reinforcement and support for muscle and tissue. The Avaulta Plus and Solo products are available in both an "anterior" and a "posterior" version, depending on the area of the pelvic floor where the mesh is intended to be implanted.

Like the other Plaintiffs in this MDL, the Plaintiffs in these bellwether cases allege that the Avaulta Plus or Solo products implanted in their bodies were negligently and defectively designed, manufactured and marketed, and that the Defendants failed to provide appropriate warnings and instructions regarding the risks and dangers posed by these devices. Plaintiffs assert product liability claims sounding in strict liability, negligence, and breach of warranty, and they also assert claims for punitive damages; their spouses assert claims for loss of consortium. (Master Complaint at ¶¶ 62-107). These bellwether Plaintiffs have each suffered serious and permanent physical injuries and physical and mental pain from the implantation of the Avaulta devices, and each of them endured additional surgical intervention to remove or revise the mesh, additional medical expenses, and unresolved complications for which the device was implanted. Both the Avaulta Plus and Solo products are constructed of polypropylene, a thermoplastic polymer. In addition, the Avaulta Plus has a "porous, acellular, ultra-thin sheet of crosslinked collagen" – processed pig skin – attached to the central portion of the polypropylene mesh. Four heavyweight mesh arms extend from the central portion of both the Avaulta Plus and Solo devices. These dense arms are implanted into tissue where they are intended to "anchor" the central portion of the mesh, which is supposed to serve as the support structure for the prolapsed organ(s).

Peer-reviewed, published scientific literature has long demonstrated that the pore size, elasticity, surface area and weight/density of the mesh are important factors in determining the biocompatibility of implantable surgical mesh devices and the propensity for mesh-related complications associated with such devices. Medical studies and Bard's own experience with other tissue repair devices demonstrated that the use of animal-derived collagen in implanted devices – such as the pig-skin collagen used in the Avaulta Plus – increases the likelihood of

chronic inflammation, fibrotic tissue reaction, and encapsulation. It is also established scientifically that polypropylene is subject to degradation and shrinkage *in vivo*. A significant number of women implanted with the Avaulta mesh devices suffer from serious injuries including recurrent and chronic pelvic pain, painful sexual intercourse (or, "dyspareunia"), chronic infections, nerve and/or vascular damage, and vaginal and other pelvic organ injury and scarring. Each of the four bellwether Plaintiffs have had to endure invasive surgical procedures in an attempt to remove mesh or pieces of mesh that have resulted in internal damage to their pelvic region.

B. Case Specific Facts Regarding Carolyn Jones

Ms. Jones brings this lawsuit for personal injuries caused by Defendant's Avaulta ® Plus Anterior and Posterior BioSynthetic Support Systems. A Bard Align sling was implanted at the same surgery (Williams Depo. at pp. 56:13-57:7).[1]

Justin Winn, Dr. Williams' Bard representative, was present almost every time Dr. Williams implanted the Product. Mr. Winn never criticized Dr. Williams' surgical technique; rather, he was complimentary of it (Williams Depo. at pp. 18:4-21, 19:1-10). After surgery, Ms. Jones followed the postoperative instructions provided to her by Dr. Williams (Jones Depo. at pp. 192:10-193:25).[2] On a follow-up visit, Dr. Williams noted a small area of exposed mesh to which he attributed her post-implant bleeding (Williams Depo. at pp. 75:25-79:19). Subsequent to the implantation of the Avaulta products and the Align sling, Ms. Jones has undergone treatment by a number of physicians, and surgery by Dr. Farmer, a urologist, Dr. Secrest, a urologist and Dr. Fox, a colorectal surgeon. All these surgeries are related to the injuries caused by the Avaulta mesh.

[1] A copy of Dr. Williams deposition is attached hereto as Exhibit 1.

[2] A copy of Ms. Jones deposition Volume I is attached hereto as Exhibit 2 and Volume II is Exhibit 3.

Ms. Jones has suffered and continues to suffer from significant pain including pelvis, rectum, back and legs, as well as urinary incontinence. She has vaginal scarring which contributes to her injuries. These injuries are substantial and will continue into the future. She will have continuing medical care and treatment for her injuries. Not all the mesh implanted in her body has been removed. Plaintiff will produce expert opinion that the cause of Ms. Jones injuries was the implantation of the Avaulta Plus Biosynthetic Anterior and Posterior Systems.

II. SUMMARY JUDGMENT STANDARD ON AFFIRMATIVE DEFENSES

In its "Answer and Affirmative Defenses" to the Master Long Form Complaint filed in this MDL, Bard asserted 53 separate "affirmative defenses." (Case 2:10-md-02187, Dkt. No. 201). Although a defendant need not prove his affirmative defense as a matter of law at the summary judgment stage, "he must point to sufficient facts in support of those defenses to create a genuine factual dispute. *E.g., Johnson v. Bd. of Regents of Univ. of Ga.*, 263 F. 3d 1234, 1264 (11th Cir. 2001) (noting that defendant has burden to adduce evidence supporting affirmative defenses and that summary judgment movant does not have burden to negate their existence)." *Nissan Motor Acceptance Corp. v. Sowega Motors, Inc.*, 2012 WL 3987417, *7 (M.D. Ga. 2012). See also *Fontenot v. Upjohn Co.*, 780 F.2d 1190, 1195 (5th Cir. 1986) ("If the movant ... does not bear the burden of proof, he should be able to obtain summary judgment simply by disproving the existence of any essential element of the opposing party's claim or affirmative defense."); *Dorris v. Accounts Receivable Mgmt., Inc.*, 2013 WL 1209629, *5 (D.Md. 2013) (defendant bears the burden of proof on summary judgment" on affirmative defense).

III. ARGUMENT AND CITATION OF AUTHORITY

A. Affirmative Defenses Nos. 6, 12 and 14: Contributory Negligence

In Mississippi, a plaintiff's own negligence will not bar his recovery, but will only operate to reduce his recovery by the percentage of the negligence attributable to him. Miss. Code. Ann. § 11-7-15 (West 2012). A plaintiff can recover some measure of damages even if he is grossly negligent. *Yazoo & M. V. R. Co. v. Williams*, 74 So. 835, 837 (1917).

In the present action, there is an absence of evidence that would support a finding that Ms. Jones was negligent or at fault in any way that contributed to or caused her injuries. Indeed, it would be difficult to conceive of a way in which a patient implanted with a medical device could be found negligent in a causal sense with respect to a device-related injury, unless there were some affirmative evidence demonstrating that that patient failed to follow her physician's instructions, and such failure to follow instructions were shown to have caused or contributed to her injuries. Even in the presence of evidence of failure to comply, the defendant would have to point to competent and admissible expert medical testimony that the patient's failure was causally related to her injuries. Here, there is no evidence of lack of compliance. To the contrary, therefore, Defendant cannot possibly carry its burden of proof at trial on this issue.

Even assuming for purposes of argument that Bard could point to any evidence of negligence by Ms. Jones that a jury could find was a medical cause of her injuries, Bard would nonetheless be unable to establish that any alleged negligent act or omission by Ms. Jones was more to blame for her own injuries than Bard's defective medical device implanted in her body. That question need not be considered here, however, in light of the fact that the record contains no evidence that Ms. Jones did anything that caused or contributed to her own injuries.

B. Affirmative Defenses Nos. 14-15 and 28: Comparative Fault of Plaintiff and Third Parties.

With regard to the comparative fault of third parties (i.e., non-defendants), Mississippi law permits the apportionment of damages amongst joint tortfeasors, including "immune" tortfeasors. Miss. Code. Ann. § 85-5-7(5) (West 2012). "[A]pportionment is an affirmative defense that must be pled and proven." *Pearl Pub. Sch. Dist. v. Groner*, 784 So. 2d 911, 916 (Miss. 2001) (emphasis added). Recently, the Mississippi Supreme Court held that the trial court properly granted the plaintiff's motion for summary judgment with respect to any individuals that were not named in the lawsuit because, even though the defendants pled apportionment as an affirmative defense, the defendants failed to provide any proof that any third party had been at fault. *Eckman v. Moore*, 876 So. 2d 975, 988-89 (Miss. 2004).

As demonstrated in the prior section on contributory negligence, there is a dearth of evidence that would establish or even suggest that Ms. Jones acted negligent in any way. Furthermore, Bard has not pointed to evidence of conduct, which if believed by the jury, would constitute negligence on the part of any non-party. Therefore, summary judgment should be granted in favor of Plaintiffs on Bard's asserted affirmative defense of comparative or non-party fault.

C. Affirmative Defense Nos. 5 and 40: Assumption of Risk

The Mississippi Products Liability Act ("MPLA") statutorily creates the assumption of risk defense in the products liability context. Miss. Code Ann. § 11-1-63(d) (West 2012). The MPLA provides that a manufacturer is not liable for its defective product if the claimant: (1) had "knowledge of a condition of the product that was inconsistent with its safety"; (2) appreciated the dangerous condition; and (3) "deliberately and voluntarily" exposed herself to the dangerous condition "in such a manner to register assent on the continuance of the dangerous condition." Miss. Code Ann. § 11-1-63(d) (West 2012).

In *Green v. Allendale Planting Co.*, the Mississippi Supreme Court noted that the MPLA assumption of risk defense "applies where a person freely and voluntary chose to encounter a

dangerous condition," and is derived from a plaintiff's 'willing' mental state. 2005-CA-02271-SCT (¶ 24) (Miss. 2007) (quoting and citing *Elias v. New Laurel Radio Station*, 146 So. 2d 558, 561 [Miss. 1962]). Notably, the inquiry is entirely subjective; whether a plaintiff assumed a particular risk "is measured by a subjective standard . . . rather than the 'reasonable man' standard." *Id.* at ¶ 31 (quoting *Hedgepeth v. Fruehauf Corp.*, 634 F. Supp. 93, 98-99 [S.D. Miss. 1986]).

Here, Bard can point to no evidence of record that Ms. Jones had knowledge that the Avaulta Plus product was defective and inconsistent with its safety, Bard can point to no evidence that Ms. Jones appreciated the dangerous condition of the product, and Bard can point to no evidence that she deliberately and voluntarily" exposed herself to the dangerous condition "in such a manner to register assent on the continuance of the dangerous condition. See Miss. Code Ann. § 11-1-63(d). Moreover, there is no evidence that Ms. Jones freely and voluntary chose to encounter a dangerous condition from a willing mental state. Therefore, summary judgment should be granted in favor of Plaintiffs on Bard's asserted affirmative defense of assumption of risk.

D. Affirmative Defense No. 5: Mitigation of Damages

In Mississippi, the failure to mitigate damages functions as an affirmative defense which must be raised by a defendant *Wall v. Swilley*, 562 So. 2d 1252, 1258 (Miss. 1990). Although an aggrieved plaintiff is not entitled to recover for damages that she did not mitigate through reasonable efforts, it is the defendant's burden to introduce facts showing that the plaintiff failed to properly mitigate her damages. *Flight Line, Inc. v. Tanksley*, 608 So.2d 1149, 1162-63 (Miss. 1992); *Royal Lincoln-Mercury Sales, Inc. v. Wallace*, 415 So. 2d 1024, 1029 (Miss. 1982) (citing *Tennessee Valley Sand & Gravel Co. v. M/V Delta*, 598 F. 2d 930 [5th Cir. 1979]). The

duty to mitigate may, for instance, require a plaintiff to follow her physician's orders *Flight Line, Inc.*, 608 So. 2d at 1162-63.

Bard can cite to no evidence that Ms. Jones failed to take reasonably diligent steps to mitigate her damages upon sustaining injuries attributable to Bard's defective product. As set forth above, Ms. Jones complied with her physician's instructions, and there is otherwise no evidence that Ms. Jones did (or failed to do) anything that could be found to have caused or exacerbated her own injuries. Bard's "mitigation of damages" defense is without factual support, and summary judgment is warranted for the Plaintiff on this defense.

E. Affirmative Defense No. 26: Federal Preemption

Defendant alleges that its conduct conformed with the Federal Food, Drug and Cosmetic Act and other federal Statutes and regulations and therefore Plaintiff's claims are barred by federal preemption. However, the Supreme Court has held that federal law does not preempt state law claims for damages in cases involving products cleared under the FDA's 510(k) process, as were all of Bard's pelvic repair mesh products. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500-01 (1996). Because there is no question of fact regarding Bard's asserted "preemption" defense, Plaintiffs are entitled to judgment as a matter of law with respect to said defense.

IV. CONCLUSION

Plaintiffs are entitled to this Partial Motion for Summary Judgment on Defendant C.R. Bard, Inc.'s affirmative defenses because there is no issue of genuine fact as to each of the aforementioned affirmative defenses. For these reasons, Plaintiffs respectfully ask that the Court grant their Partial Motion for Summary Judgment as set forth above.

This 1st day of April, 2013.

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CERTIFICATE OF SERVICE

I hereby certify that on April 1, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this M.D.L.

By: */s/ Henry G. Garrard, III*

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